

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner
 US Department of Commerce
 United States Patent and Trademark
 Office, PCT
 2011 South Clark Place Room
 CP2/5C24
 Arlington, VA 22202
 ETATS-UNIS D'AMERIQUE
 in its capacity as elected Office

Date of mailing (day/month/year) 21 May 2001 (21.05.01)	
International application No. PCT/US00/20666	Applicant's or agent's file reference 22221/1022
International filing date (day/month/year) 28 July 2000 (28.07.00)	Priority date (day/month/year) 29 July 1999 (29.07.99)
Applicant O'DONNELL, Michael, E. et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:

26 February 2001 (26.02.01)

☐ in a notice effecting later election filed with the International Bureau on:2. The election ☒ was☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer Zakaria EL KHODARY Telephone No.: (41-22) 338.83.38
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PATENT COOPERATION TREATY

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REC'D 07 JAN 2003

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

10/048071

Applicant's or agent's file reference 22221/1022	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US00/20666	International filing date (day/month/year) 28 JULY 2000	Priority date (day/month/year) 29 JULY 1999
International Patent Classification (IPC) or national classification and IPC IPC(7): C07K 1/00; C12N 1/14; C12N 3/00 and US Cl.: 530/350; 435/243, 253.4		
Applicant THE ROCKEFELLER UNIVERSITY		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets.
- ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of — sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of report with regard to novelty, inventive step or industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability, citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 26 FEBRUARY 2001	Date of completion of this report 26 NOVEMBER 2002
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer Patricia A. Duffy <i>Patricia A. Duffy</i>
Facsimile No. (703) 305-3230	Telephone No. (703) 308-0196

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US00/20666

I. Basis of the report1. With regard to the **elements** of the international application:*☒ the international application as originally filed☒ the description:pages 1-128pages NONEpages NONE, as originally filed
, filed with the demand
, filed with the letter of _____☒ the claims:pages 129-138pages NONEpages NONEpages NONE, as originally filed
, as amended (together with any statement) under Article 19
, filed with the demand
, filed with the letter of _____☒ the drawings:pages NONEpages NONEpages NONE, as originally filed
, filed with the demand
, filed with the letter of _____☒ the sequence listing part of the description:pages NONEpages NONEpages NONE, as originally filed
, filed with the demand
, filed with the letter of _____2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).☐ the language of publication of the international application (under Rule 48.3(b)).☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:☐ contained in the international application in printed form.☐ filed together with the international application in computer readable form.☐ furnished subsequently to this Authority in written form.☐ furnished subsequently to this Authority in computer readable form.☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.4. ☒ The amendments have resulted in the cancellation of:☒ the description, pages NONE☒ the claims, Nos. NONE☒ the drawings, sheets/fig NONE5. ☐ This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

**Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US00/20666

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been and will not be examined in respect of:

☐ the entire international application.

☒ claims Nos. (Please See supplemental sheet)

because:

☐ the said international application, or the said claim Nos. _ relate to the following subject matter which does not require international preliminary examination (*specify*).

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _ are so unclear that no meaningful opinion could be formed (*specify*).

☐ the claims, or said claims Nos. _ are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos. _.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☒ the computer readable form has not been furnished or does not comply with the standard.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US00/20666

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. statement**

Novelty (N)	Claims	(Please See supplemental sheet)	YES
	Claims	(Please See supplemental sheet)	NO
Inventive Step (IS)	Claims	(Please See supplemental sheet)	YES
	Claims	(Please See supplemental sheet)	NO
Industrial Applicability (IA)	Claims	(Please See supplemental sheet)	YES
	Claims	(Please See supplemental sheet)	NO

2. citations and explanations (Rule 70.7)

Claims 1-3, 7, 8, 12, 13, 17, 21, 22, 26, 30, 31, 35, 36, 40, 41, 45, 46 and 50-51 lack novelty under PCT Article 33(2) as being anticipated by Kunst et al (Nature 1997, Vol. 390 pages 249-56). The claims are drawn to DNA isolated from gram positive bacterium. Kunst et al. disclose the complete genome sequence of *Bacillus subtilis*, a gram positive bacteria and includes the open reading frames from genes as claimed (see Figure 1, III.1 DNA Replication). The recitation of "from *Streptococcus pyogenes*" or "from *Streptococcus aureus*" is not seen to differentiate the genes of the art from the claimed genes. Further, the recitation of a particular name does not distinguish one gene from another.

Claims 55-59, 60, 62-63, 65-66, 68, 70-71, 73, 75-76, 78-79, 81-82, 84-85 and 87-88 lack an inventive step under PCT Article 33(3) as being obvious over Kunst et al. in view of Yurieva et al.

Kunst et al is set forth supra. Kunst et al does not disclose the open reading frames in an expression vector, host cell or isolated proteins.

Yurieva et al teach insertion of nucleic acids encoding DNA replication proteins in an expression vector, insertion of the expression vector into a host cell, expression of the heterologous protein and isolation of the heterologous protein.

It would have been prima facie obvious to insert the nucleic acid from *Bacillus subtilis* encoding any of the open reading frames for DNA replication proteins in the expression vector of Yurieva et al, express the protein recombinantly and isolate the heterologous protein of interest because Yurieva et al teach that DNA replication proteins can be expressed recombinantly and Kunst et al teach that the proteins of *Bacillus subtilis* are potentially commercially important.

Claims 90-91 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest the claimed assay for inhibitors.

----- NEW CITATIONS -----

NONE

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US00/20666

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

Sheet 10

III. NON-ESTABLISHMENT OF REPORT:

The questions of whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect to claim numbers 4-6, 9-11, 14-16, 18-20, 23-25, 27-29, 32-34, 37-39, 42-44, 47-49, 52-54, 61, 64, 67, 69, 72, 74, 77, 80, 83, 86, 89.

V. 1. REASONED STATEMENTS:

The report as to Novelty was positive (YES) with respect to claims NONE.

The report as to Novelty was negative (NO) with respect to claims 1-3, 7, 8, 12, 13, 21, 22, 26, 30, 31, 35, 36, 40, 41, 45, 50, 51.

The report as to Inventive Step was positive (YES) with respect to claims 90-91.

The report as to Inventive Step was negative (NO) with respect to claims 1-3, 7, 8, 12-13, 17, 21-22, 26, 30-31, 35-36, 40-41, 45-46, 50-51, 55-60, 62-63, 65-66, 68, 70-71, 73, 75-76, 81-82, 84-85, 87-88.

The report as to Industrial Applicability was positive (YES) with respect to claims 1-3, 7-8, 12-13, 17, 21-23, 26, 30-31, 35-36, 40-41, 45-46, 50-51, 55-60, 62-63, 65-66, 68, 70-71, 73, 75-76, 78-79, 81-82, 84-85, 87-88, 90-91.

The report as to Industrial Applicability was negative (NO) with respect to claims NONE.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US00/20666

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☐ the said international application, or the said claim Nos. _ relate to the following subject matter which does not require international preliminary examination (*specify*).

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _ are so unclear that no meaningful opinion could be formed (*specify*).

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

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1. statement

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	Claims	(Please See supplemental sheet)	NO

2. citations and explanations (Rule 70.7)

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Claims 90-91 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest the claimed assay for inhibitors.

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NONE

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Supplemental Box

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Continuation of: Boxes I - VIII

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V. 1. REASONED STATEMENTS:

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The report as to Inventive Step was negative (NO) with respect to claims 1-3, 7, 8, 12-13, 17, 21-22, 26, 30-31, 35-36, 40-41, 45-46, 50-51, 55-60, 62-63, 65-66, 68, 70-71, 73, 75-76, 81-82, 84-85, 87-88.

The report as to Industrial Applicability was positive (YES) with respect to claims 1-3, 7-8, 12-13, 17, 21-23, 26, 30-31, 35-36, 40-41, 45-46, 50-51, 55-60, 62-63, 65-66, 68, 70-71, 73, 75-76, 78-79, 81-82, 84-85, 87-88, 90-91.

The report as to Industrial Applicability was negative (NO) with respect to claims NONE.

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